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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/800,277

03/12/2004

Thomas M. McGrath

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09/04/2007

WALTER A. HACKLER

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EXAMINER

HUSON, MONICA ANNE

ART UNIT

PAPER NUMBER

1732

MAIL DATE

DELIVERY MODE

09/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/800,277

Applicant(s)

MCGRATH ET AL.

Examiner

Monica A. Huson

Art Unit

1732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the Amendment filed 22 June 2007.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Firestone et al. (U.S. Patent 5,799,837), in view of Forte et al. (U.S. Patent Application Publication 2001/0048988). Firestone et al., hereafter "Firestone," show that it is known to carry out a method of forming a bottle useful as a pharmaceutical container and dispenser (Column 1, lines 31-38; Column 5, lines 28-31) comprising providing a mixture of polypropylene resin comprising UV absorbers (i.e. blockers) (Column 2, lines 51-54; Column 9, lines 12-13), and forming the heated UV absorbent mixture into a cylindrical squeezable bottle having a thickness of between 0.5mm and about 2mm (Column 3, lines 17-21) with a volume of 10 cc (Column 2, lines 60-61; 10mL = 10cc); disposing an ophthalmic pharmaceutical formulation into said bottle (Column 4, lines 66-67; Column 5, lines 1-11; Column 10, lines 63-64; It is being interpreted that chlorine dioxide is a known ingredient in ophthalmic pharmaceutical formulations.); and sealing the bottle (Column 12, lines 1-3). Firestone does not show a specific mixing order to obtain his mixture. However, selection of any order of mixing ingredients is prima facie obvious (See MPEP 2144.04 (IV)(C)). Also, Firestone does not specifically show first, second, and third sets of resin pellets, or providing dyestuffs to the pellets. Forte et al., hereafter "Forte," show that it is known to carry out a method of making a bottle useful as a pharmaceutical container (Para 0008), including providing combinations of polypropylenes which contain dyes in amounts enabling transmission of visual blue wavelength and UV absorbers (i.e. blockers) (Para 0015-0017; blue tinting=dye in an amount enabling transmission of visual blue wavelength; It is known in the art that individual blends of molding material, in this case, polypropylenes, will originate in pellet form, including various desired additives such as the claimed dyestuffs and UV blockers. In order to form the final molding material, the different pellet mixtures will be mixed together to form a masterbatch.),

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heating said UV blocker final mixture (Para 0024), and forming the bottle (Para 0027). Forte and Firestone are combinable because they are concerned with a similar technical field, namely, methods of forming pharmaceutical bottles. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Forte's teaching of using several blends or alloys which include dyes in the final molding composition which is molded by Firestone's general molding method after being mixed in a desired order in order to provide the blue tinting and UV protection factor for the molded article (see Forte, Para 0016-0017).

Response to Arguments

Applicant's arguments filed 22 June 2007 have been fully considered but they are not persuasive. It is noted that applicant's arguments are very similar to those filed 23 February 2007, so the examiner's response is also very similar.

Applicant contends that the teachings of Forte and Firestone do not suggest the instant invention. This is not persuasive because although applicant argues that "it is clear that in the world of dyestuffs, combinations of dyes provide unique results", there is no evidence relative to the instant invention to support this assertion. It is noted that arguments of counsel cannot take the place of evidence in the record (MPEP 2145). The article applicant has attached to supposedly support his position does not provide conclusive evidence that the steps of mixing necessarily lead to a particular result. For example, although the article purports on page 2 that the sequence in which fabric was dipped into various colors influenced what color the fabric took, this does not necessarily relate to combining the colors themselves. Also, it should be noted that the article does not even conclude with certainty that the dipping sequence or specific pigments is the cause for the unique color obtained (see paragraph 1, page 3: "*whatever* the particular shade, and *however* the Tyrians obtained it..."). Therefore, this reasoning is not persuasive, and it is maintained that it would have been obvious to carry out the instant invention in view of the teachings of Forte and Firestone.

Applicant further contends that the claimed order of mixing in the present invention should be recognized as being important with regard to resins. Applicant cites US 7124361 as showing support for this assertion. This is not persuasive because US 7124361 is not particularly related to field of the instant invention.

To further support the Examiner's position that any order of mixing resins and dyes is obvious (absent new and unexpected results), see US 4197087 which deals with combining dyes with polymers, especially note Column 5, lines 44-54. Also see US 4824905, Column 5, lines 19-40 for support that mixing order does not inherently affect a process or its outcome. It

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is maintained that varying the mixing order would be an obvious experimental change, absent new or unexpected results.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone number is 571-272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Monica A Huson

August 24, 2007